UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Shukri F. Khuri and Patrick Treanor

Application No.: 10/628,866 Filed Date: July 28, 2003

Confirmation No. 3828 Group: 3736 Examiner: Not Assigned

For: Systems and Methods of pH Tissue Monitoring

CERTIFICATE OF MAILING
I Hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
on March 22, 2004 Sharon R. Lloyd
Date Signature
Sharon R. Lloyd
Typed or printed name of person signing certificate

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

[ ] under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

[X] under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

[ ] under 37 CFR 1.97(c) together with either:
[ ] a Statement under 37 CFR 1.97(e), as checked below, or
[ ] a $180.00 fee under 37 CFR 1.17(p), or
(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)

[ ] under 37 CFR 1.97(d) together with:
[ ] a Statement under 37 CFR 1.97(e), as checked below, and
[ ] a $180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

[ ] under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

[ ] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

[ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)
Applies to original applications (other than design) filed on or after May 29, 2000

[ ] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

[X] Copies of the cited references are enclosed (AL-AQ, AL2-AQ2 and AL3, AR-AZ, AR2-AZ2, AR3-AZ3, AR4-AZ4, AR5-AW5

[ ] In accordance with 37 C.F.R. § 1.98 (d), copies of cited references (*list reference not enclosed*) are not enclosed as these references were entered in earlier application, U.S. Application No. [ ], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.

[ ] If copies of references [*list references not enclosed*] would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.

[X] Some listed references were cited in the enclosed International Search Reports in counterpart foreign applications.

Concise Explanation Requirement (non-English references):

[X] The "concise explanation" requirement (non-English references) for references AL, AM, AN, AP, AO2, AP2 under 37 CFR 1.98(a)(3) is satisfied by:
- [ ] the explanation provided on the attached sheet.
- [ ] the explanation provided in the Specification.
- [ ] submission of the enclosed International Search Report.
- [X] the enclosed English language abstract.

[ ] Applicant requests that the following pending applications be considered:

Examiner's Initials

_____ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

_____ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

_____ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

_____
Examiner Date

[ ] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account No. 50-1935 in the amount of $[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 50-1935.

Respectfully submitted,

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PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

March 22, 2004
(Use several sheets if necessary)

ATTORNEY DOCKET NO.	APPLICATION NO.
301490.1001-111	10/628,866
APPLICANT	
Shukri F. Khuri and Patrick Treanor	
FILING DATE	GROUP ART UNIT
July 28, 2003	3736

U.S. PATENT DOCUMENTS

EXAM-INER INI-TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA	3,973,555	10 Aug 1976	Möller et al	128	2	
	AB	4,252,124	24 Feb 1981	Maurer et al	128	635	
	AC	4,413,628	8 Nov 1983	Tamulis	128	635	
	AD	4,467,807	28 Aug 1984	Bornzin	128	419	
	AE	4,562,846	7 Jan 1986	Cox et al	128	696	
	AF	4,717,548	5 Jan 1988	Lee	422	68	
	AG	4,774,956	4 Oct 1988	Kruse et al	128	635	
	AH	4,912,417	27 Mar 1990	Gibboney et al	324	438	
	AI	5,024,668	18 Jun 1991	Peters	606	194	
	AJ	5,051,352	24 Sep 1991	Martindale et al	435	1	
	AK	5,063,930	12 Nov 1991	Nucci	128	632	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	TRANSLATION NO
	AL	2,198,638	1 Sep 1972	France (English Abstract)				
	AM	DE 24 48 459	24 Apr 1975	Germany (English Abstract)				
	AN	NL 7415486	31 May 1976	Netherlands (English Abstract)				
	AO	2 045 940	5 Nov 1980	Great Britain				
	AP	DE 32 43 094A1	26 May 1983	Germany (English Abstract)				
	AQ	0 354 719 A1	14 Feb 1990	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	Alam, S., et al "Lack of Effect of Nitroglycerin on the Transmural Variation of Tissue pH during Fixed Coronary Stenosis," Z. Kardiol., 72, 000-000; pp 1-4 (1983)
	AS	Axford, T.C., et al., "Electrode-derived myocardial pH measurements reflect intracellular myocardial metabolism assessed by phosphorus 31-nuclear magnetic resonance spectroscopy during normothermic ischemia," Journal of Thoracic and Cardiovascular Surgery, 103:902-907 (1992)
	AT	Dearani, J.A., et al, "Myocardial pH and Coronary Perfusion Pressure as Indicators of Survival During Cardiopulmonary Resuscitation," American College of Surgeons, Surgical Forum, 40(5):46-48 (1989)

EXAMINER	DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 22, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 301490.1001-111	APPLICATION NO. 10/628,866
	APPLICANT Shukri F. Khuri and Patrick Treanor	
	FILING DATE July 28, 2003	GROUP ART UNIT 3736

U.S. PATENT DOCUMENTS

EXAM-INER INI-TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA2	5,199,428	6 Apr 1993	Obel et al	128	419	
	AB2	5,256,660	26 Oct 1993	Swan	514	238.8	
	AC2	5,304,495	19 Apr 1994	Yim	436	68	
	AD2	5,325,709	5 Jul 1994	Lee	73	61.43	
	AE2	5,472,876	5 Dec 1995	Fahy	435	284.1	
	AF2	5,522,389	4 Jun 1996	Fischer et al	128	634	
	AG2	5,533,971	9 Jul 1996	Phipps	604	20	
	AH2	5,573,502	12 Nov 1996	LeCocq et al	604	4	
	AI2	5,588,816	31 Dec 1996	Abbott et al	417	479	
	AJ2	5,603,817	18 Feb 1997	Settler et al	204	433	
	AK2	5,753,207	19 May 1998	Zuo et al	424	9.36	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	NO
	AL2	WO 92/19150	12 Nov 1992	PCT				
	AM2	0 522 727 A1	13 Jan 1993	Europe				
	AN2	2,151,579	11 Dec 1995	Canada				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AU	Dearani, J.A., "Routine Measurement of Myocardial Temperature is Not Reflective of Myocardial Metabolism During Cardiac Surgery," American College of Surgeons, Surgical Forum, 41:228-230 (1990)
	AV	Dearani, J.A., et al, "Role of Myocardial Temperature Measurement in Monitoring the Adequacy of Myocardial Protection During Cardiac Surgery," Ann Thorac Surg, 2001; 72:S2235-44
	AW	Hassanein, W., et al., "Continuous Perfusion of Donor Hearts in the Beating State Extends Preservation Time and Improves Recovery of Function," The Journal of Thoracic and Cardiovascular Surgery, 116:821-830 (1998)
	AX	Josa, M., et al, "The Superiority of Blood Over Crystalloid Cardioplegia in Preventing Myocardial Acidosis During Global Cardiac Arrest," Cardiac Surgery, Surgical Forum, 253-255

EXAMINER	DATE CONSIDERED

PTO-1449 REPRODUCED **INFORMATION DISCLOSURE CITATION IN AN APPLICATION** March 22, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 301490.1001-11	APPLICATION NO. 10/628,866
	APPLICANT Shukri F. Khuri and Patrick Treanor	
	FILING DATE July 28, 2003	GROUP ART UNIT 3736

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA3	5,766,432	16 Jun 1998	Dunn et al	204	412	
	AB3	5,788,631	4 Aug 1998	Fiddian-Green	600	309	
	AC3	5,813,403	29 Sep 1998	Soller et al	128	633	
	AD3	5,899,867	4 May 1999	Collura	600	545	
	AE3	6,046,046	4 Apr 2000	Hassanein	435	284.1	
	AF3	6,090,096	18 Jul 2000	St. Goar et al	604	509	
	AG3	6,100,082	8 Aug 2000	Hassanein	435	284.1	
	AH3	6,113,575	5 Sep 2000	Viitala, et al	604	132	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	TRANSLATION NO
	AO2	JP 08-182665	16 Jul 1996	Japan (English Abstract)				
	AP2	FR 2 744 804	14 Aug 1997	France (English Abstract)				
	AQ2	WO 98/26709	25 Jun 1998	PCT				
	AL3	WO 99 08589	25 Feb 1999	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AY	Khabbaz, K. R. et al, "Simultaneous In Vivo Measurements of Intracellular and Extracellular Myocardial pH During Repeated Episodes of Ischemia," Current Surgery, 46(5):399-400 (1989)
	AZ	Khabbaz, K. R., et al, "Intraoperative Metabolic Monitoring of the Heart: II. Online Measurement of Myocardial Tissue pH," The Annals of Thoracic Surgery, 72:S2227-34 (2001)
	AR2	Khuri, S. F., et al., "First Report of Intramyocardial pH in Man: I. Methodology and Initial Results," Medical Instrumentation, 18(3):167-171 (1984)
	AS2	Khuri, S. F., et al, "Intraoperative assessment of the physiologic significance of coronary stenosis in humans," Journal of Thoracic and Cardiovascular Surgery, 92(1):79-87 (1986)
	AT2	Khuri, S. F., et al "First report of intramyocardial pH in man," Journal of Thoracic and Cardiovascular Surgery, 86(5):667-678 (1983)

EXAMINER	DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 22, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 301490.1001-111	APPLICATION NO. 10/628,866
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EXAM-INER INI-TIAL		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	AU2	Khuri, S.F. et al., "Metabolic Correlates of Myocardial Stunning and the Effect of Cardiopulmonary Bypass," Journal of Cardiac Surgery, 8(2):262-270 (1993)
	AV2	Khuri, S.F. et al, "The Superiority of Continuous Cold Blood Cardioplegia in the Metabolic Protection of the Hypertrophied Human Heart," Journal of Thoracic and Cardiovascular Surgery, 95(3):442-454 (1998)
	AW2	Khuri, S.F. & Marston, W.A., "On-line Metabolic Monitoring of the Heart During Cardiac Surgery," Symposium on the Latest Advances in Cardiac Surgery," Surgical Clinics of North America, 65(3):439-453 (1985)
	AX2	Khuri, S.F. & Warner, K.G., "Intraoperative pH Monitoring for the Detection of Progressive Myocardial Ischemia," Myocardial Protection in Cardiac Surgery, Arthur J. Roberts ed. (Marcel Dikker, Inc.), pp 399-412 (1987)
	AY2	Khuri, S.F. et al. "Changes in Intramyocardial ST Segment Voltage and Gas Tensions with Regional Myocardial Ischemia in the Dog," Circulation Research, 37:455-463 (1975)
	AZ2	Khuri, S.F., "Myocardial Preservation During Coronary Artery Bypass Surgery," Cardiac Surgery: State of the Art Reviews, 1(1):59-75 (1986)
	AR3	Khuri, S.F., et al, "Observations on 100 patients with continuous intraoperative monitoring of intramyocardial pH," Journal of Thoracic and Cardiovascular Surgery, 89:170-182 (1985)
	AS3	Khuri, S.F., et al "Intramural Pco_2: a reliable index of the severity of myocardial ischemic injury," American Journal Physiol., 237(2): H253-H259 (1979)
	AT3	Khuri, S.F., "Myocardial Protection During Reoperative Valve Surgery," A Textbook of Cardioplegia for Difficult Clinical Problems, Engelman Rm, Levitsky S., (Futura Publishing Company, Inc.), 21:221-235 (1992)
	AU3	Khuri, S.F., "Invited letter concerning: Changes in myocardial high-energy stores and carbohydrate metabolism during intermittent aortic crossclamping in dogs on cardiopulmonary bypass at 34° and 25° C," The Journal of Thoracic and Cardiovascular Surgery, 101(3):559-561 (1991)
	AV3	Khuri, S.F., "pH-Guided Myocardial Management: A New Frontier in Cardiac Surgery," no date given
	AW3	Khuri, S.F., et al., "The Significance of the Late Fall in Myocardial Pco_2 and Its Relationship to Myocardial pH after Regional Coronary Occlusion in the Dog," Circulation Research, 56(4):537-547 (1985)
	AX3	Khuri, S.F., et al., "Intraoperative Assessment of the Stunned versus Infarcted Myocardium with the Simultaneous Use of Transesophageal Echocardiography and the Measurement of Myocardial pH: Two Case Studies,: Journal of Cardiac Surgery, 9(3):403-409 (1994)
	AY3	Khuri, S. F., et al, "Panel Discussion: Monitoring and Improving Patient Safety During and Following Cardiac Surgery," Ann Thorac Surg 2001; 72:S2267-70
	AZ3	Kwasnik, E.M., et al., "Hemodynamic and metabolic responses to graded microvascular occlusion," Journal of Vascular Surgery, 13(6):867-874 (1991)
	AR4	Lange, R., et al, "Time Course of Ischemic Alterations during Normothermic and Hypothermic Arrest and its Reflection by On-line Monitoring of Tissue pH," Journal of Thoracic Cardiovascular Surgery, 86(3):418-434 (1983)

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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 22, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 301490.1001-111	APPLICATION NO. 10/628,866
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EXAMINER INITIAL		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	AS4	Lange, R et al, ""Intramyocardial pH Measurement: A Useful Tool for the On-line Assessment of Ischemic Damage and the Adequacy of Myocardial Preservation During Open Heart Surgery?," American College of Surgeons, Surgical Forum 33:290-292 (1982)
	AT4	Lange, R et al., "The relative important of alkalinity, temperature, and the washout effect of bicarbonate-buffered, multidose cardioplegic solution," Myocardial Protection, 70:I-75-I-83 (1984)
	AU4	Martin, D., et al., "The Effects of Normothermic and Hypothermic Cardiopulmonary Bypass on Defibrillation Energy Requirements and Transmyocardial Impedance," Journal of Thoracic and Cardiovascular Surgery, 109:981-988 (1995)
	AV4	Randolph, J. D., et al., "Improved Myocardial Preservation with Oxygenated Cardioplegic Solutions as Reflected by On-line Monitoring of Intramyocardial pH during Arrest," Journal of Vascular Surgery, 3(2):216-225 (1986)
	AW4	Reifart, N., et al., "Effects of Bepridil on Regional Myocardial Ischemia and Comparison with Verapamil," The American Journal of Cardiology, 58:541-546 (1986)
	AX4	Siouffi, S. Y. et al., "Method for the Metabolic Quantification of Regional Myocardial Ischemia," Journal of Surgical Research, 43:360-378 (1987)
	AY4	Tantillo, M.B. & Khuri, S.F., "Myocardial tissue pH in the assessment of the extent of myocardial ischemia and the adequacy of myocardial protection," Ischemia-reperfusion in cardiac surgery, H.M. Piper & C. J. Preusse (ed), (Kluwer Academic Publishers), 335-352 (1993)
	AZ4	Warner, K.G., et al, "Comparative Response of Muscle and Subcutaneous Tissue pH During Arterial and Venous Occlusion in Musculocutaneous Flaps," Annals of Plastic Surgery, 22(2):108-116 (1989)
	AR5	Warner, K.G. et al "Reduction in Myocardial Acidosis Using Blood Cardioplegia," Journal of Surgical Research, 45(3):247-256 (1987)
	AS5	Warner, K. G., et al, "Metabolic and Microscopic Evidence of Ischemia in Valvular Heart Operation: Are we Really Protecting the Hypertrophied Ventricle?," American College of Surgeons, Surgical Forum , 36:216-218 (1985)
	AT5	Warner, K. G., et al, "Structural and Metabolic correlates of cell injury in the hypertrophied myocardium during valve replacement," Journal of Thoracic and Cardiovascular Surgery, 93(5):741-754 (1987)
	AU5	Warner, K.G., et al, "Significance of the Transmural Diminution in Regional Hydrogen Ion Production After Repeated Coronary Artery Occlusions," Circulation Research, 64(3):616-628 (1989)
	AV5	Warner, K.G. et al, "Regional Changes in Myocardial Acid Production during Ischemic Arrest: A Comparison of Sanguineous and Asanguineous Cardioplegia," Annals of Thoracic Surgery, 45(1):75-81 (1988)
	AW5	Zankoul, F.E., et al, "Time Course and Significance of Myocardial Tissue Acidosis During Global Ischemia and Sanguineous Reperfusion in the Isolated Rabbit Heart," Surgical Forum, 48:353-355 (1997)

EXAMINER	DATE CONSIDERED